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Attorney Docket No. 2302-1651 (PP01651.102)

PATENT

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 2/3/04.

By: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of **RAPPUOLI et al.**

Serial No.: **10/089,367**

Examiner: **Unassigned**

Confirmation No.: _____

Art Unit: **Unassigned**

Filed: **March 28, 2002**

For: **MUCOSAL DTPa VACCINES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08A for the above-identified patent application.

- ☒ In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required.
- ☐ In accordance with 37 C.F.R. §1.97(c), also enclosed is:
 - ☐ the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
 - ☐ a statement as specified in 37 C.F.R. §1.97(e).
- ☐ In accordance with 37 C.F.R. §1.97(d), a statement as specified in 37 C.F.R. §1.97(e) and the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) are also enclosed.
- ☐ Check No. ____ in the amount of \$ ____ for the total fee is attached.

☒ [X] A return receipt postcard is also enclosed.

☐ [] Please charge \$_____ to Deposit Account No. 18-1648 for the total fee.
This paper is being submitted in duplicate.

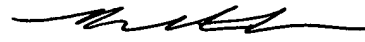
The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 18-1648.

Dated: 2/3/04

Respectfully submitted,

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By: _____



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Reg. No. 33,208



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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(b)

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.
§§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, copies of documents **A1, B1-B6, C1-C5 and C7-C22** cited in the attached Form PTO/SB/08 are enclosed.
- ☐ No copies of publications _____ listed on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. _____ to which the above-identified application claims priority under 35 U.S.C. §120.
- ☐ No copies of publications _____ are being provided pursuant Office waiver of 37 C.F.R. §1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003.

- ☐ Publication(s) _____ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to _____ application serial no. _____ and mailed on _____.
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____. English language publication ____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) ____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) ____ cited in the attached Form PTO/SB/08A.
- ☐ Enclosed is a copy of pending patent Application Serial No. _____.

This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

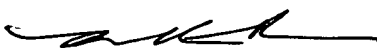
It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

Dated: 2/3/04

Respectfully submitted,

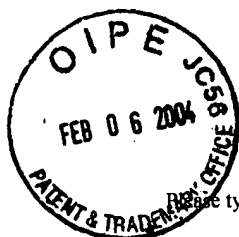
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Roberta L. Robins
Reg. No. 33,208



⁶ Applicant is to place a check mark here if English language Translation is attached.



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PTO/SB/08A (08-00)

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/089,367	
			Filing Date	March 28, 2002	
			First Named Inventor	RAPPUOLI	
			Group Art Unit	Unassigned	
			Examiner Name	Unassigned	
Sheet	2	of	4	Attorney Docket Number	2302-1651 (PP01651.102)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	C1	ALMEIDA & ALPAR, "Nasal Delivery of Vaccines", <i>J. Drug Targeting</i> <u>3</u> : 455-467.		
	C2	CAHILL et al., "Immune responses and protection against Bordetella pertussis infection after intranasal immunization of mice with filamentous haemagglutinin in solution or incorporated in biodegradable microparticles," <i>Vaccine</i> <u>13</u> :455-462, 1995.		
	C3	CAHILL et al., "Mice are protected against Bordetella pertussis infection by intra-nasal immunization with filamentous haemagglutinin," <i>FEMS Microbiology Letters</i> <u>107</u> : 211-216, 1993.		
	C4	Center for Disease Control and Prevention, "Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among InfANTS AND young Children-recommendations of the Advisory Committee on Immunization Practices (ACIP)", <i>Morbid. Mortal. Weekly Rep.</i> <u>46</u> (RR-7): 1-25, 1997.		
	C5	DEL GIUDICE et al., "Molecular basis of vaccination," <i>Molecular Aspects of Medicine</i> <u>19</u> : 1-70, 1998.		
	C7	DOUCE et al., "Mutants of Escherichia coli heat-labile toxin lacking ADP-ribosyltransferase activity act as nontoxic, mucosal adjuvants," <i>PNAS USA</i> <u>92</u> : 1644-1648, 1995.		
	C8	FONTANA et al., "Construction of nontoxic derivatives of cholera toxin and characterization of the immunological response against the A subunit," <i>Infect. Immun.</i> <u>63</u> : 2356-2360, 1995.		
	C9	GUSTAFSSON et al., "A controlled trial of a two-component acellular, a five-component acellular, and a whole-cell pertussis vaccine," <i>N. Engl. J. Med.</i> <u>334</u> : 349-355, 1996.		
	C10	GUZMAN et al., "Antibody responses in the serum and respiratory tract of mice following oral vaccination with liposomes coated with filamentous hemagglutinin and pertussis toxoid," <i>Infect. Immun.</i> <u>61</u> : 573-579, 1993.		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number.

² Applicant is to place a check mark here if English language Translation attached.

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PTO/SB/08A (08-00)

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/089,367
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First Named Inventor	RAPPUOLI
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	2302-1651 (PP01651.102)

Sheet 3 of 4

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C11	HAUSER et al., "Development and efficacy assessment of combination vaccines, with emphasis on acellular pertussis," <i>Dev. Biol. Stand.</i> <u>95</u> : 251-255, 1998.	
	C12	JONES et al., "Orally administered microencapsulated Bordetella pertussis fimbriae protect mice from B. pertussis respiratory infection," <i>Infect. Immun.</i> <u>64</u> : 489-494, 1996.	
	C13	MILLS et al., "A murine model in which protection correlates with pertussis vaccine efficacy in children reveals complementary roles for humoral and cell-mediated immunity in protection against Bordetella pertussis," <i>Infect. Immun.</i> <u>66</u> : 94-602, 1998.	
	C14	PARK et al., "The mucosal adjuvanticity of two nontoxic mutants of Escherichia coli heat-labile enterotoxin varies with immunization routes." <i>Exp. Mol. Med.</i> <u>32</u> : 72-78, 2000.	
	C15	PODDA et al., "Phase I clinical trial of an acellular pertussis vaccine composed of genetically detoxified pertussis toxin combined with FHA and 69 kDa," <i>Vaccine</i> <u>9</u> : 741-745, 1991.	
	C16	RAPPUOLI et al., "Towards third-generation whooping cough vaccines", <i>Trends in biotechnology</i> <u>9</u> : 232-238, 1991.	
	C17	RAPPUOLI, "Rational design of vaccines," <i>Nature Medicine</i> <u>3</u> : 374-376, 1997.	
	C18	RYAN et al., "The adjuvant action of mutants of the heat labile toxin of E. coli for a nasally delivered acellular pertussis vaccine," <i>Immunology Letters</i> <u>69</u> : 59, 1999.	
	C19	RYAN et al., "Mutants of Escherichia coli heat-labile toxin act as effective mucosal adjuvants for nasal delivery of an acellular pertussis vaccine: differential effects of the nontoxic AB complex and enzyme activity on Th1 and Th2 cells," <i>Infection and Immunity</i> <u>67</u> : 6270-6280, 1999.	
	C20	SHAHIN et al., "Mucosal immunization with filamentous hemagglutinin protects against Bordetella pertussis respiratory infection," <i>Infect. Immun.</i> <u>60</u> : 1482-1488, 1992.	
	C21	SHAHIN et al., "Adjuvanticity and protective immunity elicited by Bordetella pertussis antigens encapsulated in poly(DL-lactide-co-glycolide) microspheres," <i>Infect. Immun.</i> <u>63</u> : 1195-1200, 1995.	

Examiner Signature	Date Considered
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